K082908

APR 2 4 2009

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510(k) summary for the NOVAGUARD™ SAFETY NEEDLE

(as required by section 807.92)

510(k) Notification submitted by:	West Pharmaceutical Services Inc. 101 Gordon Drive Lionville, PA 19341 USA Phone: (610) 594-2900 Fax: (610) 594-3016
Contact person:	Mr. Ari Y. Sobel Director, Regulatory Affairs
Date Summary Prepared	September 30, 2008
Trade Name:	NOVAguard™ Safety Needle
Classification name:	General Hospital Class II, 80FMI Per 21 CFR 880.5570 Hypodermic Single Lumen Needle (with Antistick Feature)
Common device name:	Hypodermic needle with safety sheath or needle with needle protection device
Predicate devices:	BD ECLIPSE™ HYPODERMIC NEEDLE 510(k) No. K043397 Becton, Dickinson & Company SATETYGLIDE™ NEEDLE 510(k) No. K951254 Becton, Dickinson Vacutainer Systems Preanalytical Solutions MONOJECT™ SAFETY NEEDLE 510(k) No. K012736 Tyco Healthcare (Covidien) TERUMO SURGUARD2™ SAFETY NEEDLE 510(k) No. K040531 Terumo Medical Corp
Manufacturer:	West Pharmaceutical Services Inc. 101 Gordon Drive Lionville, PA 19341 USA

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Material:

The NOVAguard™ Safety Needle is classified as Externally Communicating Device, Blood Path Indirect, Limited Duration of Contact (< 24 hr). The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-I: Evaluation and Testing". Results of the testing demonstrate that the blood contacting materials are biocompatible and were determined suitable for the Indications for Use of this product.

Device Description:

NOVAguard™ is a sharps injury protection device with a passively activated safety shield. The NOVAguard™ product has a female luer connector, compatible with a luer-lock syringe, on one side and a stainless steel cannula on the other. A shield is mounted around the cannula. This product is packaged in a rigid container sealed by a Tyvek lid to facilitate sterilization. The product is removed from the package and connected to a luer-lock syringe simultaneously; this is accomplished when attaching the syringe, turning it in a clockwise direction. During this process, the shield is automatically moved to a position where the cannula tip is exposed so that the user can easily see it. An injection is given using the standard common technique. Inserting the cannula into the patient displaces the shield causing the shield legs to move apart and act like a spring. Upon removal, the spring force of the shield legs forces the shield over the tip of the cannula into a locked position.

The NOVAguard™ Safety Needle is an assembly of three components. A cannula, a hub and a safety shield.

Indications for Use:

The primary function of the NOVAguard™ Safety Needle is for the injection of fluids into or withdrawal of fluids from parts of the body below the surface of the skin. The needle stick prevention feature helps prevent accidental needle sticks by shielding the needle after use.

Technological comparison to Predicate Device:

The NOVAguard™ Safety Needle Indications for Use is similar to the Eclipse™, the MONOJECT™ Safety Needle and the SurGuard2™ all are intended for parenteral delivery or the withdrawal of body fluids.

All devices are compatible for use with standard luer lock syringes. Once the needle is withdrawn the safety feature is activated (either manually or automatically) and the needle should be discarded in a sharps bin. The safety needle is a single use device and should be discarded after use.

All devices are packaged sterile and designed ergonomically.

Any differences between the NOVAguard™ Safety Needle solution and the equivalent devices have no significant influence on safety or effectiveness.

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Safety and Effectiveness:

Finished products are tested and must meet all required release specifications prior to distribution. The array of testing required for release include but are not limited to; Physical testing and visual examination (in-process and finished product).

Conclusion:

It is our conclusion that the NOVAguard™ Safety Needle and its predicates are substantially equivalent in their Indications for Use, design, material, sterility and packaging.

The NOVAguard™ Safety Needle is to be used in a similar manner to the predicate devices with the exception that the NOVAguard is passive and does not require manual activation and introduces no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ari Y. Sobel
Director, Regulatory Affairs
West Pharmaceutical Services, Incorporated
101 Gordon Drive
Lionville, Pennsylvania 19341

APR 24 2009

Re: K082908
Trade/Device Name: NOVAguard™ Safety Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: April 9, 2009
Received: April 10, 2009

Dear Mr. Sobel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

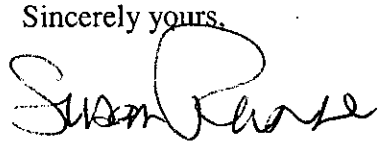
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082908

Device Name: NOVAguard™ Safety Needle

Indications for Use: The primary function of the NOVAguard™ Safety Needle is for the injection of fluids into or withdrawal of fluids from parts of the body below the surface of the skin. The needle stick prevention feature helps prevent accidental needle sticks by shielding the needle after use.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number: K082908